BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Orchid Pharma receives DCGI approval for Cefepime and Enmetazobactam antibiotic

06 June 2024 | News

Approval paves the way for launch of this advanced injectable therapy for patients in India



Orchid Pharma, based in Chennai, has received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam.

DCGI has also granted permission to manufacture and market Finished Dosage Form (FDF) of Cefepime and Enmetazobactam as a dry powder injectable. This formulation is indicated for the treatment of complicated Urinary Tract Infections (cUTI) including acute Pyelonephritis, Hospital-Acquired Pneumonia (HAP) including Ventilator-associated pneumonia (VAP), and Bacteremia when it is associated or suspected to be associated with either complicated urinary tract infections or hospital-acquired pneumonia.

With this approval, Orchid Pharma intends to improve the treatment landscape for serious infections in India, providing patients with access to advanced and effective therapy options.

This new Combination Drug provides a powerful treatment option against a range of severe infections caused by resistant bacteria, addressing a critical need in combating antimicrobial resistance.

Speaking on the approval, Manish Dhanuka, Managing Director, Orchid Pharma, said, “Enmetazobactam’s approval in India is personally fulfilling as being an Indian company, we wanted to expand access to advanced and affordable treatment options for patients in India."

The company looks forward to the successful launch and distribution of Enmetazobactam and its combination with Cefepime for enhancing the treatment landscape for severe infections in India.